



Docket No.: BBI-043CPUSCNRCE
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Jochen G. Salfeld *et al.*

Application No.: 09/801185

Confirmation No.: 1672

Filed: March 7, 2001

Art Unit: 1644

For: HUMAN ANTIBODIES THAT BIND
HUMAN TNF α

Examiner: D. A. Saunders

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT (SIDS)

MS RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In accordance with 37 CFR 1.97, Applicant hereby makes of record the following additional documents. A PTO Form SB/08 and a full copy of each of the documents required under 37 CFR 1.98a)(2) accompanying this statement. In addition, applicant notes that this application is related to U.S. Patent Nos. 6,090,382 and 6,509,015, as well as pending U.S. application 11/233252.

This statement is not to be interpreted as a representation that the cited documents are material, that an exhaustive search has been conducted, or that no other relevant information exists. Nor shall the citation of any document herein be construed *per se* as a representation that such document is prior art. Moreover, Applicant understand(s) the Examiner will make an independent evaluation of the cited documents.

This Information Disclosure Statement is filed before the mailing date of a first Office Action, and after the filing of a Request for Continued Examination (RCE) under 37 CFR 1.114 (37 CFR 1.97(b)(4)). A copy of the RCE being filed on even date herewith is enclosed.

Application No.: 09/801185

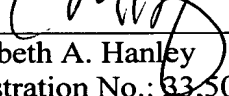
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In accordance with 37 CFR §1.97(b)(4), no additional costs are believed to be due in connection with the filing of this Information Disclosure Statement. However, please charge any necessary fees in connection with the enclosed statement to our Deposit Order Account No. 12-0080, under Order No. BBI-043CPUSCNRCE. A duplicate copy of this paper is enclosed.

Dated: December 9, 2005

GAD/EAH/CEH

Respectfully submitted,

By 
Elizabeth A. Hanley
Registration No.: 33,505
LAHIVE & COCKFIELD, LLP
28 State Street
Boston, Massachusetts 02109
(617) 227-7400
(617) 742-4214 (Fax)
Attorney/Agent For Applicant



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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 1 of 2

Complete if Known

Application Number	09/801185-Conf. #1672
Filing Date	March 7, 2001
First Named Inventor	Jochen G. SALFELD
Art Unit	1644
Examiner Name	D. A. Saunders
Attorney Docket Number	BBI-43CPUSCNRCE

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
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FOREIGN PATENT DOCUMENTS

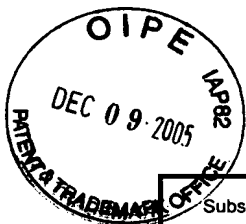
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
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NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	C1	Abraham, Edward, et al., "Efficacy and Safety of Monoclonal Antibody to Human Tumor Necrosis Factor α in Patients with Sepsis Syndrome," <i>JAMA</i> , Vol. 273(12):934-941 (1995)	
	C2	Boekstegers, P., et al., "Repeated administration of a F(ab') ₂ fragment of an anti-tumor necrosis factor alpha monoclonal antibody in patients with severe sepsis: effects on the cardiovascular system and cytokine levels," <i>Shock</i> , Vol. 1(4):237-245 (1994) (abstract from Pub Med)	
	C3	Brekke, Ole Henrik, et al., "Therapeutic antibodies for human diseases at the dawn of the twenty-first century," <i>Nature Reviews/Drug Discovery</i> , Vol. 2:52-62 (2003)	
	C4	Cohen, Jonathan, et al., "Intersept: An international, multicenter, placebo-controlled trial of monoclonal antibody to human tumor necrosis factor- α in patients with sepsis," <i>Crit Care Med</i> , Vol. 24(9):1431-1440 (1996)	
	C5	Department of Surgery, University of Toronto Annual Report, July 1, 1998 - June 30, 1999 - found online at http://www.surg.med.utoronto.ca/AnnRep/AR98_99/index.html	
	C6	Feldman, Marc, et al., "Anti-TNF α Therapy of Rheumatoid Arthritis: What Have We Learned?" <i>Annu. Rev. Immunol.</i> , Vol. 19:163-196 (2001)	
	C7	Figini, Mariangela, et al., "In Vitro Assembly of Repertoires of Antibody Chains on the Surface of Phage by Renaturation," <i>J. Mol. Biol.</i> , Vol. 239:68-78 (1994)	
	C8	Hawkins, Robert E., et al., "Selection of Phage Antibodies by Binding Affinity Mimicking Affinity Maturation," <i>J. Mol. Biol.</i> , Vol. 226:889-896 (1992)	
	C9	Holler, E., et al., "Modulation of acute graft-versus-host-disease after allogeneic bone marrow transplantation by tumor necrosis factor alpha (TNF alpha) release in the course of pretransplant conditioning: role of conditioning regimens and prophylactic application of a monoclonal antibody neutralizing human TNF alpha (MAK 195F)," <i>Blood</i> , Vol. 86(3):890-899 (1995) (abstract from Pub Med)	
	C10	Hoogenboom, Hennie R., et al., "Converting rodent into human antibodies by guided selection," <i>Antibody Engineering</i> , Oxford University Press, pp. 169-185 (1996)	
	C11	Jespers, Laurent S., et al., "Guiding the Selection of Human Antibodies from Phage Display Repertoires to a Single Epitope of an Antigen," <i>Bio/Technology</i> , Vol. 12:899-903 (1994)	

Examiner Signature	Date Considered
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				Art Unit	1644
				Examiner Name	D. A. Saunders
Sheet	2	of	2	Attorney Docket Number	BBI-43CPUSCNRCE

C12	Kempeni, Joachim, "Update on D2E7: a fully human anti-tumor necrosis factor α monoclonal antibody," <i>Ann Rheum Dis</i> , Vol. 59(Suppl. I):144-145 (2000)	
C13	Low, Nigel N., thesis extract, Cambridge University (1996)	
C14	Low, Nigel M., et al., "Mimicking Somatic Hypermutation: Affinity Maturation of Antibodies Displayed on Bacteriophage Using a Bacterial Mutator Strain," <i>J. Mol. Biol.</i> , Vol. 260:359-368 (1996)	
C15	Medynski, Dan, "Phage Display: All Dressed Up and Ready to Role," <i>Bio/Technology</i> , Vol. 12:1134-1136 (1994)	
C16	Nilsson, Björn, "Antibody engineering," <i>Current Opinion in Structural Biology</i> , Vol. 5:450-456 (1995)	
C17	Riechmann, L., et al., "Phage display and selection of a site-directed randomized single-chain antibody Fv fragment for its affinity improvement," <i>Biochemistry</i> , Vol. 32(34):8848-8855 (1993) (abstract from Pub Med)	
C18	Reinhart, K., et al., "Assessment of the safety and efficacy of the monoclonal anti-tumor necrosis factor antibody-fragment, MAK 195F, in patients with sepsis and septic shock: a multicenter, randomized, placebo-controlled, dose-ranging study," <i>Crit Care Med</i> , Vol. 24(5):1608 (1996) (abstract from Pub Med)	
C19	Santora, L.C., et al., "Characterization of Noncovalent Complexes of Recombinant Human Monoclonal Antibody and Antigen Using Cation Exchange, Size Exclusion Chromatography, and BIA core," <i>Analytical Biochemistry</i> , Vol. 299:119-129 (2001)	
C20	Thompson, J., et al., "Affinity maturation of a high-affinity human monoclonal antibody against the third hypervariable loop of human immunodeficiency virus: use of phage display to improve affinity and broaden strain reactivity," <i>J. Mol. Biol.</i> , Vol. 256(1):77-88 (1996) (abstract from Pub Med)	
C21	Van Der Poll, T., et al., "Effect of postponed treatment with an anti-tumour necrosis factor (TNF) F(ab') ₂ fragment on endotoxin-induced cytokine and neutrophil responses in chimpanzees," <i>Clin Exp Immunol</i> , Vol. 100:21-25 (1995)	
C22	Vaughan, Tristan J., et al., "Human antibodies by design," <i>Nature Biotechnology</i> , Vol. 16:535-539 (1998)	
C23	Ward, E. Sally, et al., "Binding activities of a repertoire of single immunoglobulin variable domains secreted from <i>Escherichia coli</i> ," <i>Nature</i> , Vol. 341(6242):544-546 (1989)	
C24	Winter, Greg, et al., "Making antibodies by phage display technology," <i>Annu. Rev. Immunol.</i> , Vol. 12:433-455 (1994)	

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